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ROTHWELL, FIGG, ERNST & MANBECK, P.C.  
1425 K STREET, N.W.  
SUITE 800  
WASHINGTON, DC 20005

EXAMINER

NOGUEROLA, ALEXANDER STEPHAN

ART UNIT PAPER NUMBER

1753

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/851,245

Applicant(s)

ANDERSON ET AL.

Examiner

ALEX NOGUEROLA

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-- Th MAILING DATE of this communication appears on the cover sheet with the corresponding address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 May 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3. 6) ☐ Other: \_\_\_\_\_

***Priority***

1. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 and 35 U.S.C. 121 as follows:

2. The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application); the disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994). No support has been found for claim 27 in the priority chain presented in the first paragraph on page 1 of the instant application. Only cursory reference, in discussion of current practice in the art, has been found to using film in an electrophoresis method. See the first full paragraph on page 6 and the second full paragraph on page 8 of application 08/881,761; the first full paragraph on page 6 and the second full paragraph on page 8 of application 09/339,164; and the first full paragraph on page 6 and the second full paragraph on page 8 of application 09/580,266.

*Claim Rejections - 35 USC § 112*

3. Claims 6, 8, and 9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polyacrylamide gel covalently bonded to the solid support, does not reasonably provide enablement for ionic bonding. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. The specification only discusses using Gelbond® (page 20, first full paragraph and page 8, third full paragraph), which forms a covalent bond between the gel and the substrate.

4. Claim 25 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. No description has been found in the disclosure as to how to use a cutter that is co-planar with a gel to excise portions of the gel not within the gel boundary. Figures 13A-13F, for example, show the cutter at orthogonal to the gel.

5. Claim 27 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention. Only

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cursory reference, in discussion of current practice in the art, has been found to using film in an electrophoresis method. See the second full paragraph on page 6 and the last paragraph on page 8 of the instant application

### *Double Patenting*

6. Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,451,189 in view of Minden et al. (US 6,043,025). Claim 1 of U.S. Patent No. 6,451,189 does not mention a purification step. Minden et al. teach substantially isolating a plurality of molecules of interest from a biological sample before performing two-dimensional electrophoresis. See the abstract; Figure 1; and col. 9, ll. 33-46. It would have been obvious to one with ordinary skill in the art at the time the invention was made to purify the biomolecules of interest before performing electrophoresis as taught by Minden et al. in the invention of U.S. Patent No. 6,451,189 because this will avoid introducing interferants and contaminants into the electrophoresis system. It should be noted that the first and second separation steps of claim 1 of the instant application are implied by the requirement that the gel of claim 1 of U.S. Patent No. 6,451,189 has been subjected to two-dimensional electrophoresis. Also, using a robotic device to isolate at least one of the separated biomolecules based on computer image data as optionally required by claim 1 of the instant application is implied by the requirement of claim 1 of U.S. Patent No. 6,451,189 that a selected protein is isolated in an automated fashion following analysis of the gel image.

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7. Claim 2 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,451,189 in view of Minden et al. (US 6,043,025). Claim 1 from which claim 2 depends has been addressed above. Isolating a selected biomolecule as claimed is provided in part (c) of claim 1 of U.S. Patent No. 6,451,189.

8. Claim 3 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,451,189 in view of Minden et al. (US 6,043,025). Claim 1 from which claim 3 depends has been addressed above. Claim 1 of U.S. Patent No. 6,451,189 does not mention proteins as the biomolecules, although macromolecules are indicated. Proteins are commonly separated by electrophoresis, however. Minden et al., for example, teach separating proteins. It would have been obvious to one with ordinary skill in the art at the time the invention was made to have the biomolecules (macromolecules) be proteins as taught by Minden et al. in the invention of claim 1 of U.S. Patent No. 6,451,189 because as taught by Minden et al. analysis of proteins can be a valuable source of information and a valuable diagnostic tool (col. 1, ll. 15-25).

9. Claim 4 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,451,189 in view of Minden et al. (US 6,043,025). Claim 1 from which claim 4 depends has been addressed above. Claim 1 of U.S. Patent No. 6,451,189 does not mention the type of gel used. Minden et al. use polyacrylamide (col. 10, ll. 15-22). It would have been obvious to one with ordinary skill in the

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art at the time the invention was made to use polyacrylamide as taught by Minden et al. because this will optimize the separation. Additionally, as implied by Minden et al. polyacrylamide is routinely used to separate proteins (col. 1, ll. 26-38).

10. Claim 5 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,451,189 in view of Minden et al. (US 6,043,025). Claim 4 from which claim 5 depends has been addressed above. Minden et al. perform two-dimensional SDS polyacrylamide electrophoresis (col. 10, ll. 15-22 and col. 1, ll. 26-38).

11. Claim 10 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 5 of U.S. Patent No. 6,451,189. All of the limitations of claim 10 of the instant application are stated or implied by claim 5 of U.S. Patent No. 6,451,189.

12. Claim 11 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 5 of U.S. Patent No. 6,451,189 in view of Minden et al. (US 6,043,025). Claim 10 from which claim 11 depends has been addressed above. Claim 5 of U.S. Patent No. 6,451,189 does not mention proteins as the biomolecules, although macromolecules are indicated. Proteins are commonly separated by electrophoresis, however. Minden et al., for example, teach separating proteins. It would have been obvious to one with

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ordinary skill in the art at the time the invention was made to have the biomolecules (macromolecules) be proteins as taught by Minden et al. in the invention of claim 5 of U.S. Patent No. 6,451,189 because as taught by Minden et al. analysis of proteins can be a valuable source of information and a valuable diagnostic tool (col. 1, ll. 15-25).

13. Claim 12 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 5 of U.S. Patent No. 6,451,189 in view of Minden et al. (US 6,043,025). Claim 10 from which claim 12 depends has been addressed above. Claim 5 of U.S. Patent No. 6,451,189 does not mention labeled biomolecules. Fluorescently labeled proteins are commonly separated by electrophoresis, however. Minden et al., for example, teach separating fluorescently labeled proteins (the abstract). It would have been obvious to one with ordinary skill in the art at the time the invention was made to analyze fluorescently labeled proteins as taught by Minden et al. in the invention of claim 5 of U.S. Patent No. 6,451,189 because as taught by Minden et al. analysis of proteins can be a valuable source of information and a valuable diagnostic tool (col. 1, ll. 15-25).

14. Claims 13 and 14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 5 of U.S. Patent No. 6,451,189 in view of Minden et al. (US 6,043,025). Claim 10 from which claims 13 and 14 depends have been addressed above. As seen in col. 9, ln. 46 col. 10, ln. 14 of Minden et al. the biomolecules are fluorescently stained prior to scanning



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15. Claims 15 and 16 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 5 of U.S. Patent No. 6,451,189 in view of Minden et al. (US 6,043,025). Claim 10 from which claims 15 and 16 depend have been addressed above. Minden et al. perform two-dimensional SDS polyacrylamide electrophoresis (col. 10, ll. 15-22 and col. 1, ll. 26-38).

16. Claim 17 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 5 of U.S. Patent No. 6,451,189 in view of Minden et al. (US 6,043,025) and Hochstrasser (US 5,773,645). Claim 5 of U.S. Patent No. 6,451,189 as modified by Minden et al. do not mention IPG isoelectric focusing focusing, although isoelectric focusing is taught (col. 1, ll. 26-38 and col. 10, ll. 15-22). Hochstrasser teaches two-dimensional isoelectric focusing involving IPG focusing (the abstract; col. 3, ll. 5-55; and col. 4, ll. 50-63). It would have been obvious to one with ordinary skill in the art at the time the invention was made to use an IPG gel as taught by Hochstrasser in the invention of Claim 5 of U.S. Patent No. 6,451,189 as modified by Minden et al. because this will improve the resolution along the first separation dimension.

17. Claim 23 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 5 of U.S. Patent No. 6,451,189 in view of Minden et al. (US 6,043,025). Claim 10 from which claim 23 depends has been addressed above. CCD

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detectors are commonly used in electrophoresis. Barring evidence to the contrary, the choice of detector, such as a CCD detector will depend on the sample label to be detected.

18. Claim 26 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 5 of U.S. Patent No. 6,451,189 in view of Minden et al. (US 6,043,025). Claim 10 from which claim 26 depends has been addressed above. Claim 26 just repeats steps (d) and (e) of Claim 10 for the various sample components of interest.

19. Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,507,664 in view of Minden et al. (US 6,043,025). Claim 1 of U.S. Patent No. 6,507,664 does not mention a purification step. Minden et al. teach substantially isolating a plurality of molecules of interest from a biological sample before performing two-dimensional electrophoresis. See the abstract; Figure 1; and col. 9, ll. 33-46. It would have been obvious to one with ordinary skill in the art at the time the invention was made to purify the biomolecules of interest before performing electrophoresis as taught by Minden et al. in the invention of U.S. Patent No. 6,507,664 because this will avoid introducing interferants and contaminants into the electrophoresis system. It should be noted that the first and second separation steps of claim 1 of the instant application are implied by the requirement that the gel of claim 1 of U.S. Patent No. 6,507,664 has been subjected to two-dimensional electrophoresis. Also, using a robotic device to isolate at least one of the separated biomolecules based on computer image data as optionally required by claim 1 of the instant

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application is implied by the requirement of claim 1 of U.S. Patent No. 6,507,664 that a selected protein is isolated with a device in accordance with machine-readable instructions following analysis of the gel image.

20. Claim 2 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,507,664 in view of Minden et al. (US 6,043,025). Claim 1 from which claim 2 depends has been addressed above. Isolating a selected biomolecule as claimed is provided in part (d) of claim 1 of U.S. Patent No. 6,507,664.

21. Claim 3 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,507,664 in view of Minden et al. (US 6,043,025). Claim 1 from which claim 3 depends has been addressed above. Analyzing proteins is stated through the claim; for example, see the preamble and parts (b)-(d) of claim 1 of U.S. Patent No. 6,507,664.

22. Claim 4 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,507,664 in view of Minden et al. (US 6,043,025). Claim 1 from which claim 4 depends has been addressed above. Polyacrylamide is indicated in the preamble and part (d) of claim 1 of U.S. Patent No. 6,507,664.

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23. Claim 5 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,507,664 in view of Minden et al. (US 6,043,025). Claim 4 from which claim 5 depends has been addressed above. Minden et al. perform two-dimensional SDS polyacrylamide electrophoresis (col. 10, ll. 15-22 and col. 1, ll. 26-38).

24. Claim 10 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,507,664. All of the limitations of claim 10 of the instant application are stated or implied by claim 1 of U.S. Patent No. 6,507,664.

25. Claim 11 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,507,664 in view of Minden et al. (US 6,043,025). Claim 10 from which claim 11 depends has been addressed above. Analyzing proteins is stated through the claim; for example, see the preamble and parts (b)-(d) of claim 1 of U.S. Patent No. 6,507,664.

26. Claim 12 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,507,664 in view of Minden et al. (US 6,043,025). Claim 10 from which claim 12 depends has been addressed above. Claim 1 of U.S. Patent No. 6,507,664 does not mention labeled biomolecules. Fluorescently labeled

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proteins are commonly separated by electrophoresis, however. Minden et al., for example, teach separating fluorescently labeled proteins (the abstract). It would have been obvious to one with ordinary skill in the art at the time the invention was made to analyze fluorescently labeled proteins as taught by Minden et al. in the invention of claim 1 of U.S. Patent No. 6,507,664 because as taught by Minden et al. analysis of proteins can be a valuable source of information and a valuable diagnostic tool (col. 1, ll. 15-25).

27. Claims 13 and 14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,507,664 in view of Minden et al. (US 6,043,025). Claim 10 from which claims 13 and 14 depends has been addressed above. As seen in col. 9, ln. 46 col. 10, ln. 14 of Minden et al. the biomolecules are fluorescently stained prior to scanning

28. Claims 15 and 16 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,507,664 in view of Minden et al. (US 6,043,025). Claim 10 from which claims 15 and 16 depend have been addressed above. Minden et al. perform two-dimensional SDS polyacrylamide electrophoresis (col. 10, ll. 15-22 and col. 1, ll. 26-38).

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29. Claim 17 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,507,664 in view of Minden et al. (US 6,043,025) and Hochstrasser (US 5,773,645). Claim 1 of U.S. Patent No. 6,507,664 as modified by Minden et al. do not mention IPG isoelectric focusing focusing, although isoelectric focusing is taught (col. 1, ll. 26-38 and col. 10, ll. 15-22). Hochstrasser teaches two-dimensional isoelectric focusing involving IPG focusing (the abstract; col. 3, ll. 5-55; and col. 4, ll. 50-63). It would have been obvious to one with ordinary skill in the art at the time the invention was made to use an IPG gel as taught by Hochstrasser in the invention of Claim 5 of U.S. Patent No. 6,507,664 as modified by Minden et al. because this will improve the resolution along the first separation dimension.

30. Claim 23 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,507,664 in view of Minden et al. (US 6,043,025). Claim 10 from which claim 23 depends has been addressed above. CCD detectors are commonly used in electrophoresis. Barring evidence to the contrary, the choice of detector, such as a CCD detector will depend on the sample label to be detected.

31. Claim 26 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,507,664 in view of Minden et al. (US 6,043,025). Claim 10 from which claim 26 depends has been addressed above. Claim 26 just repeats steps (d) and (e) of Claim 10 for the various sample components of interest.

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32. Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,398,932 in view of Minden et al. (US 6,043,025). Claim 1 of U.S. Patent No. 6,398,932 does not mention a purification step. Minden et al. teach substantially isolating a plurality of molecules of interest from a biological sample before performing two-dimensional electrophoresis and performing a first and a second separation step on these biomolecules. See the abstract; Figure 1; and col. 9, ll. 33-46. It would have been obvious to one with ordinary skill in the art at the time the invention was made to purify the biomolecules of interest before performing electrophoresis as taught by Minden et al. in the invention of claim 1 of U.S. Patent No. 6,398,932 because this will avoid introducing interferants and contaminants into the electrophoresis system. It would have been obvious to one with ordinary skill in the art at the time the invention was made to perform a first separation step and a second separation step as taught by Minden et al. in the invention of claim 1 of U.S. Patent No. 6,398,932 because as taught by Minden et al. "[t]wo dimensional gel electrophoresis has been a powerful tool for resolving complex mixtures of proteins" (col. 2, ll. 40-41).

Also, using a robotic device to isolate at least one of the separated biomolecules based on computer image data as optionally required by claim 1 of the instant application is implied by the requirement of claim 1 of U.S. Patent No. 6,398,932 that a selected protein is isolated with a device moved by a computer-controlled means on the basis of coordinates supplied an image processor.

33. Claim 2 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,398,932 in view of Minden et

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al. (US 6,043,025). Claim 1 from which claim 2 depends has been addressed above. Isolating a selected biomolecule as claimed is provided in part (d) of claim 1 of U.S. Patent No. 6,398,932.

34. Claim 3 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,398,932 in view of Minden et al. (US 6,043,025). Claim 1 from which claim 3 depends has been addressed above. Analyzing proteins is stated through the claim; for example, see the preamble and parts (c)-(e) of claim 1 of U.S. Patent No. 6,398,932.

35. Claim 4 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,398,932 in view of Minden et al. (US 6,043,025). Claim 1 from which claim 4 depends has been addressed above. Claim 1 of U.S. Patent No. 6,398,932 does not mention the type of gel used. Minden et al. use polyacrylamide (col. 10, ll. 15-22). It would have been obvious to one with ordinary skill in the art at the time the invention was made to use polyacrylamide as taught by Minden et al. because this will optimize the separation. Additionally, as implied by Minden et al. polyacrylamide is routinely used to separate proteins (col. 1, ll. 26-38).



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36. Claim 5 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,398,932 in view of Minden et al. (US 6,043,025). Claim 4 from which claim 5 depends has been addressed above. Minden et al. perform two-dimensional SDS polyacrylamide electrophoresis (col. 10, ll. 15-22 and col. 1, ll. 26-38).

37. Claim 10 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,398,932. All of the limitations of claim 10 of the instant application are stated or implied by claim 1 of U.S. Patent No. 6,398,932.

38. Claim 11 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,398,932 in view of Minden et al. (US 6,043,025). Claim 10 from which claim 11 depends has been addressed above. Analyzing proteins is stated through the claim; for example, see the preamble and parts (c)-(e) of claim 1 of U.S. Patent No. 6,398,932.

39. Claim 12 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 5 of U.S. Patent No. 6,398,932 in view of Minden et al. (US 6,043,025). Claim 10 from which claim 12 depends has been addressed above. Claim 5 of U.S. Patent No. 6,398,932 does not mention labeled biomolecules. Fluorescently labeled

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proteins are commonly separated by electrophoresis, however. Minden et al., for example, teach separating fluorescently labeled proteins (the abstract). It would have been obvious to one with ordinary skill in the art at the time the invention was made to analyze fluorescently labeled proteins as taught by Minden et al. in the invention of claim 5 of U.S. Patent No. 6,398,932 because as taught by Minden et al. analysis of proteins can be a valuable source of information and a valuable diagnostic tool (col. 1, ll. 15-25).

40. Claims 13 and 14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 5 of U.S. Patent No. 6,398,932 in view of Minden et al. (US 6,043,025). Claim 10 from which claims 13 and 14 depends has been addressed above. As seen in col. 9, ln. 46 col. 10, ln. 14 of Minden et al. the biomolecules are fluorescently stained prior to scanning

41. Claims 15 and 16 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,398,932 in view of Minden et al. (US 6,043,025). Claim 10 from which claims 15 and 16 depend have been addressed above. Minden et al. perform two-dimensional SDS polyacrylamide electrophoresis (col. 10, ll. 15-22 and col. 1, ll. 26-38).

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42. Claim 17 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,398,932 in view of Minden et al. (US 6,043,025) and Hochstrasser (US 5,773,645). Claim 1 of U.S. Patent No. 6,398,932 as modified by Minden et al. do not mention IPG isoelectric focusing focusing, although isoelectric focusing is taught (col. 1, ll. 26-38 and col. 10, ll. 15-22). Hochstrasser teaches two-dimensional isoelectric focusing involving IPG focusing (the abstract; col. 3, ll. 5-55; and col. 4, ll. 50-63). It would have been obvious to one with ordinary skill in the art at the time the invention was made to use an IPG gel as taught by Hochstrasser in the invention of Claim 5 of U.S. Patent No. 6,398,932 as modified by Minden et al. because this will improve the resolution along the first separation dimension.

43. Claim 22 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 4 of U.S. Patent No. 6,398,932 in view of Minden et al. (US 6,043,025). Claim 10 from which claim 22 depends has been addressed above. Claim 4 requires placing the gel onto a supporting surface.

44. Claim 23 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,398,932 in view of Minden et al. (US 6,043,025). Claim 10 from which claim 23 depends has been addressed above. CCD detectors are commonly used in electrophoresis. Barring evidence to the contrary, the choice of detector, such as a CCD detector will depend on the sample label to be detected.

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45. Claim 24 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 15 of U.S. Patent No. 6,398,932 in view of Minden et al. (US 6,043,025). Claim 10 from which claim 24 depends has been addressed above. Claim 15, which claims a cutter embodiment useable with the device of claim 1, has a support plate capable of being moved in two directions under control by a computer.

46. Claim 26 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,398,932 in view of Minden et al. (US 6,043,025). Claim 10 from which claim 26 depends has been addressed above. Claim 26 just repeats steps (d) and (e) of Claim 10 for the various sample components of interest.

*Claim Rejections - 35 USC § 103*

47. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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48. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

49. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

50. Claims 1-5, 10-16, 20, 22-24, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over JPO machine translation of Ando (JP 07260742 A) in view of Minden et al. (US 6,043,025).

Addressing Claim 1, Ando teaches a computer-assisted method for selecting and directing the isolation of one or more biomolecules in an array (the abstract), comprising  
imaging the array to generate a computer-readable output comprising, for each of a plurality of biomolecules detected in the array, a pair of x,y coordinates and a signal value;

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processing the output in at least one computer to select one or more of the detected biomolecules in accordance with previously ordained or operator-specified criteria, and

generating machine-readable instructions that direct a robotic device to isolate at least one of the selected biomolecules from the two-dimensional array.

See paragraphs [0008]-[0018] of the “Detailed Description.”

Ando do not mention performing two-dimensional electrophoresis, specifically the purification and first and second separation steps of Applicant’s claim1, although Ando does disclose electrophoresing protein (“Technical Field”).

Minden et al. teach substantially isolating biomolecules of interest from a biological sample and performing a first and a second separation step on these biomolecules. See the abstract; Figure 1; and col. 9, ll. 33-46. It would have been obvious to one with ordinary skill in the art at the time the invention was made to purify the biomolecules of interest before performing electrophoresis as taught by Minden et al. in the invention of Ando because this will avoid introducing interferants and contaminants into the electrophoresis system. It would have been obvious to one with ordinary skill in the art at the time the invention was made to perform a first separation step and a second separation step as taught by Minden et al. in the invention of Ando because as taught by Minden et al. “[t]wo dimensional gel electrophoresis has been a powerful tool for resolving complex mixtures of proteins” (col. 2, ll. 40-41).

Addressing Claim 2, isolating a selected biomolecule as claimed is implied by paragraphs [0012]-[0014] of Ando, which teaches extracting a selected biomolecule after imaging the gel.

Addressing Claims 3 and 11, Ando disclose analyzing proteins in the section entitled "Technical Field." Additionally, Minden et al. teach separating proteins. It would have been obvious to one with ordinary skill in the art at the time the invention was made to have the biomolecules (macromolecules) be proteins as taught by Minden et al. in the invention of Ando because as taught by Minden et al. analysis of proteins can be a valuable source of information and a valuable diagnostic tool (col. 1, ll. 15-25).

Addressing claim 4, Ando as modified by Minden et al. use polyacrylamide to perform the two-dimensional electrophoresis (col. 10, ll. 15-22 in Minden et al.).

Addressing Claims 5, 15, and 16, Ando as modified by Minden et al. perform two-dimensional SDS polyacrylamide electrophoresis (col. 10, ll. 15-22 and col. 1, ll. 26-38 in Minden et al.).

Addressing Claim 10, Ando teaches a computed assisted method for excising a region of a gel containing desired biomolecules from a gel (the abstract), comprising

- a) separating the desired biomolecules from undesired biomolecules in an electrophoresis gel;
- b) scanning the gel to yield a digitized image of the biomolecules in the gel;
- c) using data from the digitized image to position a cutter over the region of the gel containing the desired biomolecules wherein positioning of the cutter is computer controlled;

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d) moving the cutter into the gel to cut the region of the gel containing the desired biomolecules; and

e) lifting the cutter to lift the region of the gel containing the desired biomolecules away from the gel.

See paragraphs [0008]-[0018] of the “Detailed Description.”

Ando do not mention performing two-dimensional electrophoresis, although Ando does disclose electrophoresing protein (“Technical Field”).

Minden et al. teach substantially isolating biomolecules of interest from a biological sample and performing a first and a second separation step on these biomolecules; that is performing two-dimensional electrophoresis. See the abstract; Figure 1; and col. 9, ll. 33-46. It would have been obvious to one with ordinary skill in the art at the time the invention was made to perform two-dimensional electrophoresis taught by Minden et al. in the invention of Ando because as taught by Minden et al. “[t]wo dimensional gel electrophoresis has been a powerful tool for resolving complex mixtures of proteins” (col. 2, ll. 40-41).

Addressing Claim 12, the biomolecules in Ando as modified by Minden et al. are fluorescently labeled (the abstract).

Addressing Claims 13 and 14, as seen in col. 9, ln. 46 col. 10, ln. 14 of Minden et al. the biomolecules are fluorescently stained prior to scanning



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Addressing Claim 22, from Figure 1 of Ando the gel appears to be moved onto a supporting surface after electrophoresis is performed in device 20.

Addressing Claim 23, Ando only mentions a photoelectric multiplier; however, CCD detectors are commonly used in electrophoresis and Minden et al. in fact use a CCD detector (col. 10, ll. 24-44). It would have been obvious to one with ordinary skill in the art at the time the invention was made to use a CCD detector as taught by Minden et al. in the invention of Ando to optimize the resolution of the separated biomolecules.

Addressing Claim 24, as seen from the abstract of Ando the gel support table is movable.

Addressing Claim 26, multiple excisions is taught in paragraph [0014] of the "Detailed Description" of Ando.

51. Claims 6-9, 18, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over JPO machine translation of Ando (JP 07260742 A) in view of Minden et al. (US 6,043,025) as applied to claims 1-5, 10-16, 22-24, and 26 above, and further in view of Lugojan (US 5,543,023) and Allen et al. (US 4,746,551).

Addressing claims 6, 7, and 18, Ando as modified by Minden et al. do not appear to mention the composition of the gel support used. Glass and plastic are the most commonly used materials from which gel supports are made. If a glass support is used then the polyacrylamide

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will covalently bond to the support (col. 3, ll. 1-3 in Allen et al.). If the support is made of another material, such as plastic, it would have been obvious to one with ordinary skill in the art at the time the invention was made to bond the gel to the support, using, for example, Gelbond®, as taught by Lugojan (col. 4, ll. 29-37) because then the gel will not slide about, which could distort the imaging of the gel or the isolation of selected biomolecules.

Addressing Claim 8, Ando as modified by Minden et al. perform fluorescence gel imaging (claim 2 of Ando and col. 10, ll. 23-45 in Minden et al.).

Addressing Claims 9 and 19, it would have been obvious to one with ordinary skill in the art at the time the invention was made to use a glass support because it is readily available, since it is commonly used for electrophoresis, inexpensive, transparent, and inherently forms a bond with the gel.

52. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over JPO machine translation of Ando (JP 07260742 A) in view of Minden et al. (US 6,043,025) as applied to claims 1-5, 10-16, 22-24, and 26 above, and further in view of Hochstrasser (US 5,773,645). Ando as modified by Minden et al. do not mention IPG isoelectric focusing, although isoelectric focusing is taught (col. 1, ll. 26-38 and col. 10, ll. 15-22). Hochstrasser teaches two-dimensional isoelectric focusing involving IPG focusing (the abstract; col. 3, ll. 5-55; and col. 4, ll. 50-63). It would have been obvious to one with ordinary skill in the art at the time the invention was made

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to use an IPG gel as taught by Hochstrasser in the invention of Ando as modified by Minden et al. because this will improve the resolution along the first separation dimension.

53. Claims 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over JPO machine translation of Ando (JP 07260742 A) in view of Minden et al. (US 6,043,025) and Hochstrasser (US 5,773,645) as applied to claim 17 above, and further in view of Lugojan (US 5,543,023) and Allen et al. (US 4,746,551).

Addressing Claim 20, Ando as modified by Minden et al. and Hochstrasser do not appear to mention the composition of the gel support used. Glass and plastic are the most commonly used materials from which gel supports are made. If a glass support is used then the polyacrylamide will covalently bond to the support (col. 3, ll. 1-3 in Allen et al.). If the support is made of another material, such as plastic, it would have been obvious to one with ordinary skill in the art at the time the invention was made to bond the gel to the support, using, for example, Gelbond®, as taught by Lugojan (col. 4, ll. 29-37) because then the gel will not slide about, which could distort the imaging of the gel or the isolation of selected biomolecules.


Addressing Claim 21, it would have been obvious to one with ordinary skill in the art at the time the invention was made to use a glass support because it is readily available, since it is commonly used for electrophoresis, inexpensive, transparent, and inherently forms a bond with the gel.

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54. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (703) 305-5686. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (703) 308-3322. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

  
Alex Noguera  
April 5, 2003